

Complete Summary

GUIDELINE TITLE

Long-acting reversible contraception: the effective and appropriate use of long-acting reversible contraception.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Women's and Children's Health, National Institute for Health and Clinical Excellence. Long-acting reversible contraception: the effective and appropriate use of long-acting reversible contraception. London (UK): Royal College of Obstetricians and Gynecologists (RCOG); 2005 Oct. 167 p. [451 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
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BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
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SCOPE

DISEASE/CONDITION(S)

Unintended pregnancy

GUIDELINE CATEGORY

Counseling
Prevention

CLINICAL SPECIALTY

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Patients
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To enable women to make an informed choice about long-acting reversible contraception (LARC) and address consumer preferences
- To offer best practice advice for all women of reproductive age who may wish to regulate their fertility through the use of long-acting reversible contraceptive methods and to consider specific issues for the use of these methods in women during the menarche and before the menopause
- To identify specific issues that may be relevant to particular groups, including women with human immunodeficiency virus (HIV), learning disabilities and physical disabilities, and under-16s

TARGET POPULATION

- All women of reproductive age who may wish to regulate their fertility through the use of long-acting reversible contraceptive (LARC) methods
- Special populations considered include:
 - Women with human immunodeficiency virus (HIV)
 - Women with learning or physical disabilities
 - Women under 16 years of age

Note: The guideline does not include any contraception for men because there are currently no long-acting reversible methods. The guideline does not cover methods of contraception that are intended to result in permanent sterilisation. Contraceptive methods that are related to coitus or that require frequent (more than once per cycle (month) for women) repeat administration - for example, the combined oral contraceptive (COC) pill or progestogen-only pills - are also not included. Post-coital or emergency contraceptive methods including intrauterine device (IUD) insertion for that use are also not covered. The use of these technologies for non-contraceptive reasons (such as heavy menstrual bleeding or hormone replacement therapy) is outside the scope of this guideline.

INTERVENTIONS AND PRACTICES CONSIDERED

1. Counseling and provision of information about all contraceptive methods and offering a choice of all methods
 - Giving verbal and written information on failure rate, benefits, risks, etc.

- Offering support with decision-making
- Giving advice on safer sex
- 2. Assessment of medical, family, reproductive, and sexual history; identification of any contraindications
- 3. Provision of long-acting reversible contraception, including:
 - Copper intrauterine devices (IUDs)
 - Intrauterine system (IUS)
 - Progestogen-only injectable contraceptives (POICs)
 - Depot medroxyprogesterone acetate (DMPA)
 - Norethisterone enantate (NET-EN)
 - Progestogen-only subdermal implants (POSDIs)
 - Implanon®
- 4. Follow-up and investigation and management of problems

MAJOR OUTCOMES CONSIDERED

- Failure rate (i.e., pregnancy per 100 women-years)
- Impact on menstrual bleeding
- Discontinuation rate of long-acting reversible contraception
- Acceptability of method
- Impact on longer-term reproductive health
- Side effects
- Risk of thromboembolic disease
- Cost-effectiveness of contraceptive methods

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search Strategy

The aim of the literature review was to identify and synthesise relevant published evidence. However, evidence submitted by stakeholder organisations was considered and, if relevant to the clinical questions and of equivalent or better quality than evidence identified in the literature searches, was also included. Relevant guidelines produced by other development groups were identified using internet resources, including the National Guideline Clearinghouse, Scottish Intercollegiate Guideline Network (SIGN) and Turning Research into Practice (TRIP). The reference lists in these guidelines were checked against subsequent searches to identify missing evidence.

Evidence to answer the clinical questions formulated and agreed by the Guideline Development Group (GDG) was identified using biomedical databases via the OVID platform. Searches were performed using relevant medical subject headings and free-text terms. No language restrictions were applied to the searches. Both generic and specially developed search filters were employed when necessary.

Databases searched were MEDLINE (1966 onwards), EMBASE (1980 onwards), Cochrane Central Register of Controlled Trials (4th Quarter 2004), Cochrane Database of Systematic Reviews (4th Quarter 2004), Database of Abstracts of Review of Effects (4th Quarter 2004), and Cumulative Index to Nursing & Allied Health Literature (1982 onwards). POPLINE®, a specialist reproduction database maintained by Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs, was also utilised.

Searches to identify economic studies were undertaken using the above databases, as well as the Health Economic Evaluations Database and the National Health Service Economic Evaluations Database.

There was no systematic attempt to search grey literature (conferences, abstracts, theses and unpublished trials). Hand searching of journals not indexed on the biomedical databases was not carried out.

A preliminary scrutiny of titles and abstracts was undertaken and full copies of publications that addressed the clinical questions were obtained. Following a critical appraisal of each publication, studies that did not report relevant outcomes or were not relevant to a particular clinical question were excluded.

Searches were rerun at the end of the guideline development process, thereby including evidence published and included in the literature databases up to 1 February 2005. Any evidence published after this date was not considered for inclusion. This date should be considered for the starting point for searching for new evidence for future updates to this guideline.

Further details of literature searches can be obtained from the National Collaborating Centre for Women's and Children's Health (NCC-WCH).

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1++: High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High-quality systematic reviews of case-control or cohort studies; or high quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+: Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that relationship is causal

2-: Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3: Non-analytic studies (for example, case reports, case-series)

4: Expert opinion, formal consensus

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Synthesis of Clinical Effectiveness Evidence

Evidence relating to clinical effectiveness was reviewed using established guides and classified using the established hierarchical system described in "Rating Scheme for the Strength of the Evidence." This system reflects the susceptibility to bias that is inherent in particular study designs.

The type of clinical question dictates the highest level of evidence that may be sought. In assessing the quality of the evidence, each paper receives a quality rating coded as '++', '+' or '-'. For issues of therapy or treatment, the highest possible level of evidence (EL) is a well-conducted systematic review or meta-analysis of randomised controlled trials (RCTs) (EL = 1++) or an individual RCT (EL = 1+). Studies of poor quality are rated as '-'. Usually, studies rated as '-' should not be used as a basis for making a recommendation, but they can be used to inform recommendations. For issues of prognosis, the highest possible level of evidence is a cohort study (EL = 2-).

For each clinical question, the highest available level of evidence was selected. Where appropriate, for example, if a systematic review, meta-analysis or RCT existed in relation to a question, studies of a weaker design were not included. Where systematic reviews, meta-analyses and RCTs did not exist, other appropriate experimental or observational studies were sought. For diagnostic tests, test evaluation studies examining the performance of the test were used if the efficacy of the test was required, but where an evaluation of the effectiveness of the test in the clinical management of patients and the outcome of disease was required, evidence from RCTs or cohort studies was used.

In contraception research, investigators have not attempted to directly measure the true efficacy of a contraceptive method, compared with a control group using

no method, because ethical concerns do not permit the withholding of contraception. For this guideline, the selection criteria for including studies as a source of evidence were based on the comparability of the study population and contraceptive devices to that of the UK, as determined to be appropriate by the Guideline Development Group.

Evidence was synthesised qualitatively by summarising the content of identified papers in evidence tables and agreeing brief statements that accurately reflected the evidence. Quantitative synthesis (meta-analysis) was performed where appropriate.

Summary results and data are presented in the guideline text. More detailed results and data are presented in the accompanying evidence tables. Where possible, dichotomous outcomes are presented as relative risks (RRs) with 95% confidence intervals (CIs), and continuous outcomes are presented as mean differences with 95% CIs or standard deviations (SDs). Meta-analyses based on dichotomous outcomes are presented as pooled odds ratios (ORs) with 95% CIs, and meta-analyses based on continuous outcomes are presented as weighted mean differences (WMDs) with 95% CIs.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus
Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Guideline Development Group

The guideline was developed by a multi-professional and lay working group (the Guideline Development Group or GDG) convened by the National Collaborating Centre for Women's and Children's Health (NCC-WCH). Membership included: two consumers, two general practitioners, two family planning nurses, three specialist family planning doctors and one genitourinary medicine physician.

Staff from the NCC-WCH provided methodological support for the guideline development process, undertook systematic searches, retrieval and appraisal of the evidence, and wrote successive drafts of the guideline.

Forming and Grading Recommendations

For each clinical question, recommendations were derived using, and explicitly linked to, the evidence that supported them. Initially guideline recommendations were based on an informal consensus. Consensus was achieved at formal GDG meetings to finalise the agreement of recommendations and audit criteria.

Each recommendation was graded according to the level of evidence upon which it was based using the established system shown under "Rating Scheme for the Strength of the Recommendations." For issues of therapy or treatment, the best possible level of evidence (a systematic review or meta-analysis or an individual

randomised clinical trial [RCT]) would equate to a grade A recommendation. For issues of prognosis, the best possible level of evidence (a cohort study) would equate to a grade B recommendation. However, this should not be interpreted as an inferior grade of recommendation because it represents the highest level of relevant evidence. Indirect evidence on contraceptive devices not licensed in the UK was extrapolated to form recommendations reflecting a lower grading.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of Recommendations

A:

- At least one meta-analysis, systematic review, or randomised controlled trial (RCT) that is rated as 1++, and is directly applicable to the target population, *or*
- A systematic review of RCTs or a body of evidence that consists principally of studies rated as 1+, is directly applicable to the target population and demonstrates overall consistency of results, *or*
- Evidence drawn from a National Institute for Health and Clinical Excellence (NICE) technology appraisal

B:

- A body of evidence that includes studies rated as 2++, is directly applicable to the target population and demonstrates overall consistency of results, *or*
- Extrapolated evidence from studies rated as 1++ or 1+

C:

- A body of evidence that includes studies rated as 2+, is directly applicable to the target population and demonstrates overall consistency of results, *or*
- Extrapolated evidence from studies rated as 2++

D:

- Evidence level 3 or 4, *or*
- Extrapolated evidence from studies rated as 2+, *or*
- Formal consensus

D(GPP):

- A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group

COST ANALYSIS

Health Economics

The aim of the economic input to the guideline was to inform the Guideline Development Group (GDG) of potential economic issues related to long-acting

reversible contraception (LARC). The objective was to assess the relative cost effectiveness between LARC methods and other contraceptive methods that were considered as relevant comparators by the GDG. For this purpose, a systematic review of the economic literature was undertaken, together with a cost effectiveness analysis based on a decision-analytic economic model that was developed for this guideline.

The search strategies adopted for the systematic review were designed to identify any economic study related to LARC. Abstracts of all papers identified were reviewed by the health economists and were excluded if they did not relate to the economic questions being considered in the guideline. The relevant papers were retrieved and critically appraised. Potentially relevant references in the bibliographies of the reviewed papers were also identified and reviewed. All papers reviewed were assessed by the health economists against standard quality criteria for economic evaluation.

The decision-analytic model was developed by the health economists with the support of the GDG, who provided guidance on the data needed to populate the model and on the assumptions required to make appropriate comparisons. Full details on the methodology, the structure of the model and the underlying assumptions, the data used (clinical effectiveness and UK-based cost data), the range of values used in the sensitivity analysis, as well as the full results of the economic analysis are presented in Chapter 8 of the original guideline document.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was validated through two consultations.

1. The first draft of the guideline (The full guideline, National Institute for Clinical Excellence (NICE) guideline and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG)
2. The final consultation draft of the Full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, and 4) and recommendation grades (A-D and D(GPP)) are defined at the end of the "Major Recommendations" field.

Contraceptive Use and Principles of Care

Contraceptive Provision

D(GPP) - Women requiring contraception should be given information about and offered a choice of all methods, including long-acting reversible contraception (LARC) methods.

D(GPP) - Women should be provided with the method of contraception that is most acceptable to them provided it is not contraindicated.

C - Contraceptive service providers should be aware that:

- All currently available LARC methods (intrauterine devices [IUDs], the intrauterine system [IUS], injectable contraceptives and implants) are more cost effective than the combined oral contraceptive pill even at 1 year of use
- IUDs, the IUS and implants are more cost effective than the injectable contraceptives
- Increasing the uptake of LARC methods will reduce the number of unintended pregnancies

Provision of Information and Informed Choice

D(GPP) - Women considering LARC methods should receive detailed information - both verbal and written - that will enable them to choose a method and use it effectively. This information should take into consideration their individual needs and should include:

- Contraceptive efficacy
- Duration of use
- Risks and possible side effects
- Non-contraceptive benefits
- The procedure for initiation and removal/discontinuation
- When to seek help while using the method

D(GPP) - Counselling about contraception should be sensitive to cultural differences and religious beliefs.

D(GPP) - Healthcare professionals should have access to trained interpreters for women who are not English speaking, and to advocates for women with sensory impairments or learning disabilities.

Contraceptive Prescribing

D(GPP) - A medical history - including relevant family, menstrual, contraceptive and sexual history - should be taken as part of the routine assessment of medical eligibility for individual contraceptive methods.

D(GPP) - Healthcare professionals helping women to make contraceptive choices should be familiar with nationally agreed guidance on medical eligibility and recommendations for contraceptive use.

D(GPP) - When considering choice of LARC methods for specific groups of women and women with medical conditions, healthcare professionals should be aware of and discuss with each woman any issues that might affect her choice.

D(GPP) - Healthcare professionals should exclude pregnancy by taking the menstrual and sexual history before initiating any contraceptive methods.

D(GPP) - Healthcare professionals should supply an interim method of contraception at the first appointment if required.

D(GPP) - Healthcare professionals should ensure that informed consent is obtained from the woman whenever any method of LARC is being used outside the terms of the United Kingdom (UK) Marketing Authorisation. This should be discussed and documented in the notes.

D(GPP) - Women who have a current venous thromboembolism (VTE) and need hormonal contraception while having treatment for the VTE should be referred to a specialist in contraceptive care.

Contraception and Sexually Transmitted Infection

D(GPP) - Healthcare professionals providing contraceptive advice should promote safer sex.

D(GPP) - Healthcare professionals providing contraceptive advice should be able to assess risk for sexually transmitted infections (STIs) and advise testing when appropriate.

D(GPP) - Healthcare professionals should be able to provide information about local services for STI screening, investigation and treatment.

Contraception for Special Groups

D(GPP) - Healthcare professionals should be aware of the law relating to the provision of advice and contraception for young people and for people with learning disabilities. Child protection issues and the Fraser guidelines should be considered when providing contraception for women younger than 16 years.*

**Note: See the Department of Health's [Best Practice Guidance for Doctors and Other Health Professionals on the Provision of Advice and Treatment to Young People under 16 on Contraception, Sexual and Reproductive Health](http://www.dh.gov.uk) (July 2004), available from www.dh.gov.uk.*

D(GPP) - Women with learning and/or physical disabilities should be supported in making their own decisions about contraception.

D(GPP) - Contraception should be seen in terms of the needs of the individual rather than in terms of relieving the anxieties of carers or relatives.

D(GPP) - When a woman with a learning disability is unable to understand and take responsibility for decisions about contraception, carers and other involved

parties should meet to address issues around the woman's contraceptive need and to establish a care plan.

Training of Health Professionals in Contraceptive Care

D(GPP) - Healthcare professionals advising women about contraceptive choices should be competent to:

- Help women to consider and compare the risks and benefits of all methods relevant to their individual needs
- Manage common side effects and problems

D(GPP) - Contraceptive service providers who do not provide LARC in their practice or service should have an agreed mechanism in place for referring women for LARC.

D(GPP) - Healthcare professionals providing intrauterine or subdermal contraceptives should receive training to develop and maintain the relevant skills to provide these methods.

C - IUDs and the IUS should only be fitted by trained personnel with continuing experience of inserting at least one IUD or one IUS a month.

D(GPP) - Contraceptive implants should be inserted and removed only by healthcare professionals trained in the procedure.

Copper Intrauterine Devices

Decision Making

Women should be given the following information.

Contraceptive Efficacy

- **C** - IUDs act by preventing fertilisation and inhibiting implantation.
- **D** - The licensed duration of use for IUDs containing 380 mm² copper ranges from 5 to 10 years, depending on the type of device.
- **C** - The pregnancy rate associated with the use of IUDs containing 380 mm² copper is very low (fewer than 20 in 1000 over 5 years).
- **C** - There is no evidence of a delay in the return of fertility following removal or expulsion of IUDs.

Effect on Periods

- **C** - Heavier bleeding and/or dysmenorrhoea are likely with IUD use.

Risks and Possible Side Effects

- **C** - Up to 50% of women stop using IUDs within 5 years; the most common reasons for discontinuation are unacceptable vaginal bleeding and pain.

- **C** - There is no evidence that IUD use affects weight.
- **C** - Any changes in mood and libido are similar whether using IUDs or the IUS, and the changes are small.
- **D** - The risk of uterine perforation at the time of IUD insertion is very low (less than 1 in 1000).
- **C** - The risk of developing pelvic inflammatory disease following IUD insertion is very low (less than 1 in 100) in women who are at low risk of STIs.
- **C** - IUDs may be expelled but this occurs in fewer than 1 in 20 women in 5 years.
- **D** - The risk of ectopic pregnancy when using IUDs is lower than when using no contraception.
- **C** - The overall risk of ectopic pregnancy when using the IUD is very low, at about 1 in 1000 in 5 years.
- **C** - If a woman becomes pregnant with the IUD in situ, the risk of ectopic pregnancy is about 1 in 20, and she should seek advice to exclude ectopic pregnancy.

Other Issues to Consider before Fitting an IUD

D - Women who are aged 40 years or older at the time of IUD insertion may retain the device until they no longer require contraception, even if this is beyond the duration of the UK Marketing Authorisation.*

*Note: Check the Summary of Product Characteristics of individual devices for current licensed indications. Informed consent is needed when using outside the licensed indications. This should be discussed and documented in the notes.

D(GPP) - Contraceptive care providers should be aware that the risk of perforation is related to the skill of the healthcare professional inserting the IUD.

D(GPP) - Testing for the following infections should be undertaken before IUD insertion:

- *Chlamydia trachomatis* in women at risk of STIs
- *Neisseria gonorrhoeae* in women from areas where the disease is prevalent and who are at risk of STIs
- Any STIs in women who request it

D(GPP) - If testing for STIs is not possible, or has not been completed, prophylactic antibiotics should be given before IUD insertion in women at increased risk of STIs.

D(GPP) - Women with identified risks associated with uterine or systemic infection should have investigations, and appropriate prophylaxis or treatment before insertion of an IUD.

Specific Groups, Medical Conditions and Contraindications

D(GPP) - IUDs may be used by adolescents, but STI risk should be considered where relevant.

Healthcare professionals should be aware that:

- **D(GPP)** - IUD use is not contraindicated in nulliparous women of any age.
- **D(GPP)** - Women of all ages may use IUDs.
- **C** - IUDs can safely be used by women who are breastfeeding.

Healthcare professionals should be aware that:

- **D(GPP)** - IUD use is not contraindicated in women with diabetes.
- **D(GPP)** - IUD use is a safe and effective method of contraception for women who are human immunodeficiency virus (HIV)-positive or have acquired immune deficiency syndrome (AIDS) (safer sex using condoms should be encouraged in this group).

Practical Details of Fitting IUDs

B - The most effective IUDs contain at least 380 mm² of copper and have banded copper on the arms. This, together with the licensed duration of use, should be considered when deciding which IUD to use.

D(GPP) - Provided that it is reasonably certain that the woman is not pregnant, IUDs may be inserted:

- At any time during the menstrual cycle
- Immediately after first- or second-trimester abortion, or at any time thereafter
- From 4 weeks postpartum, irrespective of the mode of delivery

D(GPP) - Emergency drugs including anti-epileptic medication should be available at the time of IUD insertion in a woman with epilepsy because there may be an increased risk of a seizure at the time of cervical dilation.

Advice for Women at Time of Fitting

D(GPP) - Women should be informed:

- About symptoms of uterine perforation or infection that would warrant an early review of IUD use
- That insertion of an IUD may cause pain and discomfort for a few hours and light bleeding for a few days, and they should be informed about appropriate pain relief
- About how to check for the presence of IUD threads and encouraged to do this regularly with the aim of recognising expulsion

Follow-Up and Managing Problems

D(GPP) - A follow-up visit should be recommended after the first menses, or 3-6 weeks after insertion, to exclude infection, perforation or expulsion. Thereafter, a woman should be strongly encouraged to return at any time to discuss problems, if she wants to change her method of contraception, or if it is time to have the IUD removed.

B - Heavier and/or prolonged bleeding associated with IUD use can be treated with nonsteroidal anti-inflammatory drugs and tranexamic acid.

D(GPP) - Women who find heavy bleeding associated with IUD use unacceptable may consider changing to a levonorgestrel intrauterine system (LNG-IUS).

D(GPP) - The presence of *Actinomyces*-like organisms on a cervical smear in a woman with a current IUD requires an assessment to exclude pelvic infection. Routine removal is not indicated in women without signs of pelvic infection.

D(GPP) - Women who have an intrauterine pregnancy with an IUD *in situ* should be advised to have the IUD removed before 12 weeks' completed gestation, whether or not they intend to continue the pregnancy.

Intrauterine System

Decision Making

Women should be given the following information.

Contraceptive Efficacy

- **D(GPP)** - The IUS may act predominantly by preventing implantation and sometimes by preventing fertilisation.
- **C** - The pregnancy rate associated with the use of the IUS is very low (fewer than 10 in 1000 over 5 years).
- **D** - The licensed duration of use for IUS is 5 years for contraception.
- **C** - There is no evidence of a delay in the return of fertility following removal or expulsion of the IUS.

Effects on Periods

- **C** - Irregular bleeding and spotting are common during the first 6 months following IUS insertion.
- **C** - Oligomenorrhoea or amenorrhoea is likely by the end of the first year of IUS use.

Risks and Possible Side Effects

- **C** - Up to 60% of women stop using the IUS within 5 years. The most common reasons are unacceptable vaginal bleeding and pain; a less common reason is hormonal (non-bleeding) problems.
- **C** - There is no evidence that IUS use causes weight gain.
- **C** - Any changes in mood and libido are similar whether using the IUS or IUDs, and the changes are small.
- **C** - There may be an increased likelihood of developing acne as a result of absorption of progestogen, but few women discontinue IUS use for this reason.
- **D** - The risk of uterine perforation at the time of IUS insertion is very low (less than 1 in 1000).

- **C** - The risk of developing pelvic inflammatory disease following IUS insertion is very low (less than 1 in 100) in women who are at low risk of STIs.
- **C** - The IUS may be expelled, but this occurs in fewer than 1 in 20 women in 5 years.
- **D** - The risk of ectopic pregnancy when using the IUS is lower than when using no contraception.
- **C** - The overall risk of ectopic pregnancy when using the IUS is very low, at about 1 in 1000 in 5 years.
- **D(GPP)** - If a woman becomes pregnant with the IUS *in situ*, the risk of ectopic pregnancy is about 1 in 20, and she should seek advice to exclude ectopic pregnancy.

Other Issues to Consider Before Fitting an IUS

D - Women who are aged 45 years or older at the time of IUS insertion and who are amenorrhoeic may retain the device until they no longer require contraception, even if this is beyond the duration of UK Marketing Authorisation.*

*Note: Check the Summary of Product Characteristics for current licensed indications. Informed consent is needed when using outside the licensed indications. This should be discussed and documented in the notes.

D(GPP) - Contraceptive care providers should be aware that the risk of perforation is related to the skill of the healthcare professional inserting the IUS.

D(GPP) - Testing for the following infections should be undertaken before IUS insertion:

- *Chlamydia trachomatis* in women at risk of STIs
- *Neisseria gonorrhoeae* in women from areas where the disease is prevalent and who are at risk of STIs
- Any STIs in women who request it

D(GPP) - If testing for STIs is not possible, or has not been completed, prophylactic antibiotics should be given before IUS insertion in women at increased risks of STIs.

D(GPP) - Women with identified risks associated with uterine or systemic infection should have investigations, and appropriate prophylaxis or treatment before insertion of the IUS.

Specific Groups, Medical Conditions and Contraindications

D(GPP) - The IUS may be used by adolescents, but STI risk should be considered where appropriate.

Healthcare professionals should be aware that:

- **D(GPP)** - IUS use is not contraindicated in nulliparous women of any age.
- **D(GPP)** - Women of all ages may use the IUS.

- **D** - The IUS can safely be used by women who are breastfeeding.

Healthcare professionals should be aware that:

- **D** - There is no evidence that the effectiveness of the IUS is reduced when taking any other medication.
- **D(GPP)** - IUS use is not contraindicated in women with diabetes.
- **D(GPP)** - IUS is a safe and effective method of contraception for women who are HIV-positive or have AIDS (safer sex using condoms should be encouraged in this group).
- **D(GPP)** - All progestogen-only methods, including the IUS, may be used by women who have migraine with or without aura.
- **D(GPP)** - Women with a history of venous thromboembolism may use the IUS.
- **D(GPP)** - IUS is medically safe for women to use if oestrogen is contraindicated.

Practical Details of Fitting the IUS

D(GPP) - Provided that it is reasonably certain that the woman is not pregnant, the IUS may be inserted:

- At any time during the menstrual cycle (but if the woman is amenorrhoeic or it has been more than 5 days since menstrual bleeding started, additional barrier contraception should be used for the first 7 days after insertion)
- Immediately after first- or second-trimester abortion, or at any time thereafter
- From 4 weeks postpartum, irrespective of the mode of delivery.*

*Note: At the time of publication (October 2005), use before 6 weeks postpartum was outside the UK marketing authorisation for the IUS. Check the Summary of Product Characteristics for current licensed indications. Informed consent is needed when using outside the licensed indications. This should be discussed and documented in the notes.

D(GPP) - Emergency drugs including anti-epileptic medication should be available at the time of IUS insertion in a woman with epilepsy because there may be an increased risk of a seizure at the time of cervical dilation.

Advice for Women at Time of Fitting

Women should be informed:

- **D(GPP)** - About symptoms of uterine perforation or infection that would warrant an early review of IUS use
- **D(GPP)** - That insertion of an IUS may cause pain and discomfort for a few hours and light bleeding for a few days, and they should be informed about appropriate pain relief
- **D(GPP)** - About how to check for the presence of IUS threads, and encouraged to do this regularly with the aim of recognising expulsion.

Follow-up and Managing Problems

D(GPP) - A follow-up visit should be recommended after the first menses, or 3-6 weeks after insertion, to exclude infection, perforation or expulsion. Thereafter, a woman should be strongly encouraged to return at any time to discuss problems, if she wants to change her method of contraception, or if it is time to have the IUS removed.

D(GPP) - The presence of *Actinomyces*-like organisms on a cervical smear in a woman with a current IUS requires an assessment to exclude pelvic infection. Routine removal is not indicated in women without signs of pelvic infection.

D(GPP) - Women with an intrauterine pregnancy with an IUS *in situ* should be advised to have the IUS removed before 12 completed weeks of gestation whether or not they intend to continue the pregnancy.

Progestogen-Only Injectable Contraceptives (POICs)

Decision Making

Women should be given the following information.

Contraceptive Efficacy

- **C** - Progestogen-only injectable contraceptives act primarily by preventing ovulation.
- **C** - The pregnancy rate associated with injectable contraceptives, when given at the recommended intervals, is very low (fewer than 4 in 1000 over 2 years) and the pregnancy rate with depot medroxyprogesterone acetate (DMPA) is lower than that with norethisterone enantate (NET-EN).
- **C** - DMPA should be repeated every 12 weeks and NET-EN every 8 weeks*.

* Note: At the time of publication (October 2005), NET-EN was not licensed for long-term use. Check the Summary of Product Characteristics for current licensed indications. Informed consent is needed when using outside the licensed indications. This should be discussed and documented in the notes.

- **C** - There could be a delay of up to 1 year in the return of fertility after stopping the use of injectable contraceptives.
- **D(GPP)** - If a woman stops using injectable contraceptives but does not wish to conceive, she should start using a different contraceptive method immediately even if amenorrhoea persists.

Effects on Periods

- **C** - Amenorrhoea is likely during use of injectable contraceptives; this is more likely with DMPA than NET-EN, is more likely as time goes by, and is not harmful.
- **C** - Up to 50% of women stop using DMPA by 1 year; the most common reason for discontinuation is an altered bleeding pattern, including persistent bleeding.

Risks and Possible Side Effects

- **C** - DMPA use may be associated with an increase of up to 2-3 kg in weight over 1 year.
- **C** - DMPA use is not associated with acne, depression or headaches.
- **B** - DMPA use is associated with a small loss of bone mineral density, which is largely recovered when DMPA is discontinued.
- **B** - There is no evidence that DMPA use increases the risk of fracture.

Other Issues to Consider before Giving Injectable Contraceptives

Specific Groups, Medical Conditions and Contraindications

Because of the possible effect on bone mineral density, care should be taken in recommending DMPA to:

- **D(GPP)** - Adolescents, but it may be given if other methods are not suitable or acceptable.**
- **D(GPP)** - Women older than 40 years, but in general the benefits outweigh the risks, and it may be given if other methods are not suitable or acceptable.**

**Note: Refer to Committee on Safety of Medicines (CSM) advice issued in November 2004. Go to www.mrha.gov.uk and search for Depo Provera.

Healthcare professionals should be aware that:

- **D(GPP)** - Women with a body mass index over 30 can safely use DMPA and NET-EN
- **C** - Women who are breastfeeding can consider using injectable contraceptives.

Healthcare professionals should be aware that:

- **D(GPP)** - All progestogen only-methods, including injectable contraceptives, may be used by women who have migraine with or without aura
- **D(GPP)** - DMPA is medically safe for women to use if oestrogen is contraindicated
- **D(GPP)** - Injectable contraceptives are not contraindicated in women with diabetes
- **D(GPP)** - DMPA use may be associated with a reduction in the frequency of seizures in women with epilepsy
- **D(GPP)** - There is no evidence that DMPA use increases the risk of STI or HIV acquisition
- **D(GPP)** - DMPA is a safe and effective method of contraception for women with STIs, including HIV/AIDS (safer sex using condoms should be encouraged in this group)
- **D(GPP)** - Women taking liver enzyme-inducing medication may use DMPA and the dose interval does not need to be reduced.

Practical Details of Giving Injectable Contraceptives

D(GPP) - Injectable contraceptives should be given by deep intramuscular injection into the gluteal or deltoid muscle or the lateral thigh.

D(GPP) - Provided that it is reasonably certain that the woman is not pregnant, the use of injectable contraceptives may be started:

- Up to and including the fifth day of the menstrual cycle without the need for additional contraceptive protection
- At any other time in the menstrual cycle, but additional barrier contraception should be used for the first 7 days after the injection
- Immediately after first- or second-trimester abortion, or at any time thereafter
- At any time postpartum

Follow-Up and Managing Problems

D(GPP) - Women attending up to 2 weeks late for repeat injection of DMPA may be given the injection without the need for additional contraceptives.*

*Note: At the time of publication (October 2005), this use was outside the UK marketing authorisation. Check the Summary of Product Characteristics for current licensed indications. Informed consent is needed when using outside the licensed indications. This should be discussed and documented in the notes.

C - A pattern of persistent bleeding associated with DMPA use can be treated with mefenamic acid or ethinylestradiol.

D(GPP) - Women who wish to continue DMPA use beyond 2 years should have their individual clinical situations reviewed, the balance between the benefits and potential risks discussed, and be supported in their choice of whether or not to continue.**

**Note: Refer to Committee on Safety of Medicines advice issued in November 2004. Go to www.mhra.gov.uk and search for Depo Provera.

D(GPP) - Healthcare professionals should be aware that if pregnancy occurs during DMPA use there is no evidence of congenital malformation to the fetus.

Progestogen-Only Subdermal Implants (POSDIs)

Decision Making

Women should be given the following information.

Contraceptive Efficacy

- **C** - Implanon® acts by preventing ovulation.
- **C** - The pregnancy rate associated with the use of Implanon is very low (fewer than 1 in 1000 over 3 years).

- **D** - Implanon has UK Marketing Authorisation for use for 3 years.
- **C** - There is no evidence of a delay in the return of fertility following removal of contraceptive implants.

Effects on Periods

- **C** - Bleeding patterns are likely to change while using Implanon.
- **C** - 20% of women will have no bleeding, while almost 50% of women will have infrequent, frequent or prolonged bleeding.
- **C** - Bleeding patterns are likely to remain irregular over time.
- **C** - Dysmenorrhoea may be reduced during the use of Implanon.

Risks and Possible Side Effects

- **C** - Up to 43% of women stop using Implanon within 3 years; 33% of women stop because of irregular bleeding and less than 10% of women stop for other reasons including hormonal (non-bleeding) problems.
- **C** - Implanon use is not associated with changes in weight, mood, libido or headaches.
- **C** - Implanon use may be associated with acne.

Other Issues to Consider Before Fitting an Implant

Specific Groups, Medical Conditions and Contraindications

Healthcare professionals should be aware that:

- **C** - There is no evidence that the effectiveness or adverse effects of implants vary with the age of the user
- **D(GPP)** - Women over 70 kg can use Implanon as an effective method of contraception
- **C** - Contraceptive implants can safely be used by women who are breastfeeding.

Healthcare professionals should be aware that:

- **D(GPP)** - Implanon use is not contraindicated in women with diabetes
- **D(GPP)** - There is no evidence that implant use increases the risk of STI or HIV acquisition
- **D(GPP)** - Contraceptive implants are a safe and effective method of contraception for women with STI, including HIV/AIDS (safer sex using condoms should be encouraged in this group)
- **D(GPP)** - All progestogen-only methods, including contraceptive implants, may be used by women who have migraine with or without aura
- **C** - Contraceptive implants are medically safe for women to use if oestrogen is contraindicated
- **C** - There is no evidence of an effect of Implanon use on bone mineral density.
- **D** - Implanon is not recommended as a contraceptive method for women taking liver enzyme-inducing drugs.

Practical Details of Fitting Implants

D(GPP) - Provided that it is reasonably certain that the woman is not pregnant, Implanon may be inserted:

- At any time (but if the woman is amenorrhoeic or it has been more than 5 days since menstrual bleeding started, additional barrier contraception should be used for first 7 days after insertion)
- Immediately after abortion in any trimester
- At any time postpartum

Advice for Women at Time of Fitting

C - Women should be informed that Implanon insertion and removal both cause some discomfort and bruising but that technical problems are unusual (less than 1 in 100).

Follow-up and Managing Problems

D(GPP) - No routine follow-up is needed after implant insertion. However, a woman should be strongly encouraged to return at any time to discuss problems, if she wants to change her method of contraception, or if it is time to have the implant removed.

B - Irregular bleeding associated with implant use can be treated with mefenamic acid, ethinylestradiol.

D(GPP) - There is no evidence of a teratogenic effect of Implanon use but, if a woman becomes pregnant and continues with the pregnancy, the implant should be removed.

D(GPP) - If an Implanon implant cannot be palpated (due to deep insertion, failed insertion or migration) it should be localised by ultrasound investigation before being removed. Deeply inserted implants often need to be removed by an expert.

Definitions:

Levels of Evidence

1++: High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High-quality systematic reviews of case-control or cohort studies; or high quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+: Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that relationship is causal

2-: Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3: Non-analytic studies (for example, case reports, case-series)

4: Expert opinion, formal consensus

Classification of Recommendations

A:

- At least one meta-analysis, systematic review, or randomised controlled trial (RCT) that is rated as 1++, and is directly applicable to the target population, *or*
- A systematic review of RCTs or a body of evidence that consists principally of studies rated as 1+, is directly applicable to the target population and demonstrates overall consistency of results, *or*
- Evidence drawn from a National Institute for Health and Clinical Excellence (NICE) technology appraisal

B:

- A body of evidence that includes studies rated as 2++, is directly applicable to the target population and demonstrates overall consistency of results *or*
- Extrapolated evidence from studies rated as 1++ or 1+

C:

- A body of evidence that includes studies rated as 2+, is directly applicable to the target population and demonstrates overall consistency of results, *or*
- Extrapolated evidence from studies rated as 2++

D:

- Evidence level 3 or 4, *or*
- Extrapolated evidence from studies rated as 2+, *or*
- Formal consensus

D(GPP): A good

- A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group

CLINICAL ALGORITHM(S)

The algorithm "Effective and appropriate use of long-acting reversible contraception" is provided in the original guideline document and "The care

pathway" algorithm is provided in the quick reference guide. (See "Availability of Companion Documents" field for more information on the quick reference guide.)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Expert clinical opinion is that long-acting reversible contraception (LARC) methods may have a wider role and an increase in their use could help to reduce unintended pregnancy.

POTENTIAL HARMS

Side effects of long-acting reversible contraceptives (LARCs), may include irregular bleeding, pain, acne, ectopic pregnancy, weight gain, and bone thinning.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Implanon is not recommended as a contraceptive method for women taking liver enzyme-inducing drugs.
- The sexual behaviour of potential users of contraception has relevance to method choice. For example, the intrauterine device (IUD) is relatively contraindicated for a woman with multiple partners.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- While every effort has been made to ensure the accuracy of the information contained within this publication, the publisher can give no guarantee for information about drug dosage and application thereof contained in this book. In every individual case the respective user must check current indications and accuracy by consulting other pharmaceutical literature and following the guidelines laid down by the manufacturers of specific products and the relevant authorities in the country in which they are practising.
- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of

the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation in the National Health Service (NHS)

Resource Implications

Local health communities should review their existing practice for long-acting reversible contraception (LARC) against this guideline. The review should consider the resources required to implement the recommendations, the people and processes involved, and the timeline over which full implementation is envisaged. It is in the interests of patients that the implementation is as rapid as possible.

Information on the cost impact of this guideline in England will be available on the National Institute for Health and Clinical Excellence (NICE) website from November 2005, and includes a template that local communities can use (<http://guidance.nice.org.uk/CG30/costtemplate/xls/English>). A slide set is also available.

General

The Department of Health considers implementation of clinical guidelines to be a developmental standard and this will be monitored by the Healthcare Commission. The implementation of this guideline should form part of the service development plans for each local health community in England and Wales.

There are no current National Health Service (NHS) guidelines covering this topic that are widely used or tailored to cover United Kingdom (UK) practice. This guideline intends to complement other existing and proposed works of relevance, including *A strategic framework for sexual health in Wales*, the *National strategy for sexual health and human immunodeficiency virus (HIV)*, and the subsequent implementation plan.

Audit

Suggested audit criteria based on the key priorities for implementation are listed in Appendix D of the NICE version of the guideline, and can be used to audit practice locally.

Key Priorities for Implementation

The following recommendations have been identified as priorities for implementation.

Contraceptive Provision

- Women requiring contraception should be given information about and offered a choice of all methods, including long-acting reversible contraception (LARC) methods.
- Contraceptive service providers should be aware that:
 - All currently available LARC methods (intrauterine devices, the intrauterine system, injectable contraceptives and implants) are more cost effective than the combined oral contraceptive pill even at 1 year of use
 - Intrauterine devices, the intrauterine system and implants are more cost effective than the injectable contraceptives
 - Increasing the uptake of LARC methods will reduce the numbers of unintended pregnancies.

Counselling and Provision of Information

- Women considering LARC methods should receive detailed information – both verbal and written – that will enable them to choose a method and use it effectively. This information should take into consideration their individual needs and should include:
 - Contraceptive efficacy
 - Duration of use
 - Risks and possible side effects
 - Non-contraceptive benefits
 - The procedure for initiation and removal/discontinuation
 - When to seek help while using the method

Training of Healthcare Professionals in Contraceptive Care

- Healthcare professionals advising women about contraceptive choices should be competent to:
 - Help women to consider and compare the risks and benefits of all methods relevant to their individual needs
 - Manage common side effects and problems
- Contraceptive service providers who do not provide LARC within their own practice or service should have an agreed mechanism in place for referring women for LARC.
- Healthcare professionals providing intrauterine or subdermal contraceptives should receive training to develop and maintain the relevant skills to provide these methods.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
 Clinical Algorithm
 Patient Resources
 Quick Reference Guides/Physician Guides
 Resources
 Slide Presentation

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Women's and Children's Health, National Institute for Health and Clinical Excellence. Long-acting reversible contraception: the effective and appropriate use of long-acting reversible contraception. London (UK): Royal College of Obstetricians and Gynecologists (RCOG); 2005 Oct. 167 p. [451 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Oct

GUIDELINE DEVELOPER(S)

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National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All Guideline Development Group (GDG) members' interests were recorded on a standard declaration form that covered consultancies, fee-paid work, shareholdings, fellowships, and support from the healthcare industry in accordance with guidance from the National Institute for Health and Clinical Excellence (NICE).

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- National Collaborating Centre for Women's and Children's Health. Long-acting reversible contraception. London (UK): National Institute for Health and Clinical Excellence (NICE); 2005 Oct. 47 p. (Clinical guideline; no. 30). Electronic copies: Available in Portable Document Format (PDF) from the [NICE Web site](#).
- Long-acting reversible contraception. Quick reference guide. National Collaborating Centre for Women's and Children's Health, 2005 Oct. 11 p. Electronic copies: Available from the [NICE Web site](#).
- National cost-impact report. Implementing the NICE clinical guideline on long-acting reversible contraception. 2005 Dec. 33 p. Available from the [NICE Web site](#).
- Costing template. Long-acting reversible contraception. 2005 Oct. Available from the [NICE Web site](#).
- Presenter slides: Long-acting reversible contraception. 2005 Oct. Available from the [NICE Web site](#).

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, quoting reference no: N0916, or from the National Health Service at 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Long-acting reversible contraception. Understanding NICE guidance. National Institute for Health and Clinical Excellence (NICE), 2005 Oct. 4 p.

Electronic copies: Available in Portable Document Format (PDF) from the [NICE Web site](#).

Print copies: Available from the National Health Service (NHS), 11 Strand, London, WC2N 5HR or from the NHS Response Line 0870 1555 455, quoting reference no. N0916.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on January 18, 2006. The information was verified by the guideline developer on September 11, 2006.

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